



## COVID-19 Testing Consent

Concentric by Ginkgo, a service provided by Ginkgo Bioworks, Inc. ("Concentric"), is providing COVID-19 testing programs in the form of "pooled testing" and/or "diagnostic tests" to schools and organizations (a "Program"). The pooled tests offered through a Program were validated using FDA recommendations. It shows if anyone in a "pool" is sick. However, the test does not show specifically who is sick. Diagnostic tests show if a particular individual is sick. The diagnostic tests offered through a program are FDA-authorized and include rapid antigen tests and PCR/molecular tests.

**Each participant must read and sign this form before taking part in a Program.** If the participant is a under the age of 18 ("Minor"), a parent or legal guardian must read and sign this form on behalf of the Minor before the Minor's participation in a Program.

### Key highlights of the consent are:

- Like most COVID-19 tests, neither the pooled nor diagnostic tests used in this program are FDA-approved. (Note: The word "approved" means a very specific thing in the eyes of the FDA. As of early 2021, no COVID-19 tests have been approved by the FDA.)
- Pooled tests do not provide individual results for each person in a pool. However, if a positive result is produced from a pooled test, all persons in that pool will be notified.
- Individual diagnostic tests may be used as "follow-up tests" if a pooled test produces a positive result. They may also be used on their own. The school or organization providing the test under the program will determine when and how diagnostic testing will be used.
- Since diagnostic tests do provide individual results, each person will be notified of each result from every diagnostic test he/she/they perform.
- You can revoke your consent at any time.
- Potential risks from collecting a sample include slight discomfort.

### **Please carefully read and sign the following Consent**

Throughout the consent, "you" and "your" refer to the person whose information and sample(s) is/are being provided for testing and who will receive the services as may be provided under a Program ("Test Taker"). **By signing this consent, you confirm that you are the Test Taker or the appropriate parent, guardian, or legally authorized individual to provide consent for the below named Minor Test Taker and:**

- A. You authorize the collection and testing of pooled COVID-19 tests and /or individual diagnostic tests as requested by Test Taker's organization or school on the Test Taker (including rapid antigen tests and PCR/molecular tests). You understand that all sample types will be non-invasive, short nasal swabs or saliva. Potential risks from sample collection include discomfort from the insertion of the swabs. The irritation is expected to be brief.
- B. You understand that pooled tests of this type are not required to be approved or authorized by the U.S. Food & Drug Administration (FDA), and You understand pooled tests are not an FDA approved or authorized test nor a medical diagnostic test. You understand that individual diagnostic tests provided by Concentric are FDA authorized under an emergency use authorization.
- C. You understand that pooled testing does not yield individual results for each member of a pool, and that the results of the Test Taker's *individual* results within a pooled test cannot be shared with you. You understand the Test Taker's organization or school may receive the results of any test.



- D. You understand that you will be notified about the results of any individual diagnostic PCR or molecular test for COVID-19.
- E. You understand that, as with any COVID-19 test, there is the potential for a false positive or false negative COVID-19 test result and that the potential for an errant COVID-19 test result may be higher with pooled testing than individual testing.
- F. You understand that neither Concentric nor the Test Taker’s school or Organization is acting as the Test Taker’s medical provider, this testing does not replace treatment by the Test Taker’s medical provider, and you assume complete and full responsibility to take appropriate action with regards to the Test Taker’s test results. You will not make medical decisions without consulting a healthcare provider or disregard medical advice from your healthcare provider or delay seeking such advice based on the test results you receive from pooled or individual testing.
- G. You understand that you can change your mind and cancel this permission at any time, but such cancellation is forward-looking only, and will not affect information you already permitted to be released. To cancel this permission for COVID-19 testing, contact The Test Taker’s School or Organization.
- H. You understand that Concentric is researching aspects of the COVID-19 virus, such as tracking viral mutations and you further authorize Concentric to sequence viruses and other microbes present in the samples for epidemiological and public health purposes.

You, the undersigned, confirm you have read the above information about the Program, the description of the test samples to be collected, and possible risks of the Program and you understand that this information may also be provided by Concentric upon written request to the Test Taker’s school or organization. Additional terms and conditions, Concentric’s privacy policy, and release authorizations for Concentric testing can be found here: <https://www.concentricbyginkgo.com/consent>. You voluntarily agree to participate (or allow Minor to participate) in the Program.

School/Organization Name: \_\_\_\_\_

<b>If this consent is for you as the Test Taker</b>	<b>If this consent is for a Minor:</b>
Name (print): _____ Signature: _____ Date: _____	Minor’s Name (print): _____ Parent/Legal Guardian Name (print): _____ Parent/Legal Guardian Signature: _____ Date: _____

<p>_____ I do not consent/authorize COVID-19 pooled testing for my child.            Parent Signature: _____</p>
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